

510(k) Summary

JUL 20 2009

510(k) Sponsor: DermaPort, Inc.
25102 Rye Canyon Loop
Suite 110
Santa Clarita, CA 91355

Device Name: PVAS™ Ported Vascular Access System

510(k) Contact: Jennifer Hessel, Director RA/QA
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Fax: (661) 362-7902
Email: jhessel@dermaport.com

Summary Date: June 10, 2009

Trade Name: DermaPort Ported Vascular Access System (PVAS™)

Common Name: Hemodialysis Catheter, Implanted

Classification Name: 21 CFR 876.5540 Blood Access Device and Accessories, Class III,
Product Code: MSD

Predicate Device:
510(k) Number: K071202
Manufacture: DermaPort
Trade Name: Percutaneous Vascular Access System (PVAS)

1.0 Description of Device

The Ported Vascular Access System (PVAS™) has been developed to support central vascular access for hemodialysis and apheresis. This application is for the addition of a 15.5F catheter to the PVAS system and a dilating lead-in to replace the sheath during insertion.

The PVAS port consists of a percutaneous tubular conduit, through which a standard 14.5F or 15.5F polyurethane hemodialysis catheter enters the subcutaneous tunnel. An integral seal surrounds the catheter and prevents microbial migration along the catheter. The PVAS port is enclosed by a silicone anchor that braces the assembly to the skin, and an associated brake holds the catheter in place within the port. A tissue integrating biomaterial surrounds the port, providing anatomical fixation and prevention of microbial migration in a manner analogous to the Dacron cuff of a tunneled catheter.

1.1 Clinical Application

The clinical application of the DermaPort Ported Vascular Access System and catheter is consistent with clinical applications of the predicate DermaPort Percutaneous Vascular Access System cleared to market by 510(k) K071202.

2.0 Intended Use of Device

The indication for use of the PVAS is consistent with the classification of 21 CFR 876.5540 Blood Access Device and Accessories. The indication for use is:

The DermaPort Ported Vascular Access System (PVAS™) is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.

3.0 Technological Characteristics

The technical characteristics of the Ported Vascular Access System (PVAS™) are the same as the predicate devices in terms of intended use, insertion method, design, materials, performance, labeling, manufacturing process, and method of sterilization. The modifications include: addition of 15.5F catheters incorporation of dilating lead-in, removal of the sheath, replacement of non-valved dilator with a valved dilator, addition of suture to the kit, and replacement of polycarbonate injection caps with ABS injection caps

4.0 Data Summary

The design differences were tested to verify the removal of the sheath, addition of dilating lead-in, change in mesh geometry, 15.5 F catheter and new or modified accessories did not impact the function, performance or safety of the device. The performance testing performed to verify these changes consisted of insertion testing, histopathological analysis of the mesh following implantation in a chronic animal model, biomechanical testing of tissue ingrowth, mesh to port removal force for modified geometry, catheter/port retention testing, microbial ingress and flow versus pressure for new catheter sizes and functional/biocompatibility testing for new accessories. The test methods used to evaluate these changes were equivalent to those applied to the predicate device.

5.0 Conclusions

The modifications to the DermaPort PVAS were evaluated as required by the risk analysis and Design Control requirements. The modified PVAS does not raise new questions of safety or effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2009

Ms. Jennifer Hessel
Director, Regulatory Affairs and Quality Assurance
DermaPort, Inc.
25102 Rye Canyon Loop, Suite 110
SANTA CLARITA CA 91355

Re: K091760

Trade/Device Name: DermaPort Ported Vascular Access System (PVAS)
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: July 13, 2009
Received: July 15, 2009

Dear Ms. Hessel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

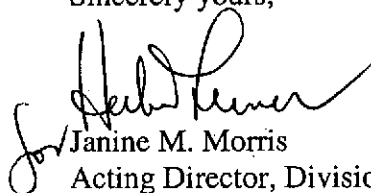
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (301) 796-5484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 301-796-6045. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name.

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number (if known): K091760

Device Name: DermaPort Ported Vascular Access System (PVAS)

Indications for Use:

The DermaPort Ported Vascular Access System (PVAS™) is indicated for long-term (greater than 30 days) vascular access for hemodialysis and apheresis. The system is inserted percutaneously and typically placed in the internal jugular vein of an adult patient. The subclavian vein is an alternate catheter insertion site.

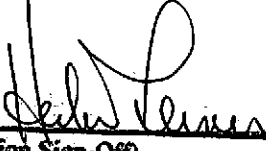
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091760